DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Rockville MD 20857

APR 25 2002

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Stephen Paul Mahinka
Counsel to BASF AG
Morgan, Lewis & Bockius, L.L.P.
1800 M Street, N.W.
Washington, D.C. 20036

Re: Docket No. 78N-0038
Comment No. CP2, SUP 9, SUP 10, SUP 12, and SUP 19

Dear Mr. Mahinka:

This letter concerns your citizen petition (CP) (undated) filed on May 30, 1989, and additional information to support the petition submitted on March 21, 1990, June 28, 1990, September 13, 1990, and October 13, 1995. The petition is filed in the Dockets Management Branch under Docket No. 78N-0038 on May 25, 1989.

Since your petition was submitted, the agency has informed you and other interested parties that it was developing a process by which drugs without any marketing experience in the United States could become eligible for consideration in the agency's over-the-counter (OTC) drug review. We are pleased to inform you that the process is now being implemented.

This process is described in a final rule entitled "Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded," which was published in the Federal Register of January 23, 2002 (67 FR 3060). A copy is enclosed for your information. This final rule is effective on February 22, 2002.

The final rule requires the submission of a Time and Extent Application (TEA) (see § 330.14(c)) to request consideration under the OTC drug review. The required information and format for a TEA are set out in the final rule (see § 330.14(c)). Three copies of the TEA are to be submitted to the Central Document Room (see § 330.14(d)).

If you wish to pursue inclusion in the OTC drug monograph system of an OTC drug product or active ingredient that was the subject of your CP, please submit a TEA in the required format. We do not intend to take further action on your CP.

As stated in comment 20 of the final rule that established the TEA process, the agency will

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give priority to TEA's associated with pending CP's if those CP's are converted to TEA's that are submitted within 120 days after publication of that final rule.

We look forward to reviewing your TEA upon submission.

Sincerely yours,

Dennis E. Baker
Associate Commissioner
for Regulatory Affairs

Enclosure

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 4·26·02

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 78N-0038

TO: Dockets Management Branch, HFA-305

[X] The attached material should be placed on public display under the above referenced Docket No.

[X] This material should be cross-referenced to Comment No. CP2 & SUP9 & SUP10 & SUP12 & SUP19

Charles J. Ganley, M.D.

Attachment